Proposed Decision Memo for Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse (CAG-00427N)

Decision Summary

The Centers for Medicare and Medicaid Services (CMS) proposes the following:

The evidence is adequate to conclude that screening and behavioral counseling to reduce alcohol misuse, which is recommended with a grade of B by the U.S. Preventive Services Task Force (USPSTF) for adults, including pregnant women, in primary care settings, is reasonable and necessary for the prevention of early illness or disability, and is appropriate for individuals entitled to benefits under Part A or enrolled under Part B.

Therefore CMS proposes to cover annual alcohol screening and for those that screen positive, up to four brief, face-to-face, behavioral counseling interventions per year for Medicare beneficiaries, including pregnant women:

- Who misuse alcohol, but whose levels or patterns of alcohol consumption do not meet criteria for alcohol dependence (defined as at least three of the following: tolerance; withdrawal symptoms; impaired control; preoccupation with acquisition and/or use; persistent desire or unsuccessful efforts to quit; sustains social, occupational, or recreational disability; use continues despite adverse consequences); and
- Who are competent and alert at the time that counseling is provided; and
- Whose counseling is furnished by qualified primary care physicians or other primary care practitioners in a primary care setting.

Each of the behavioral counseling interventions should be consistent with the 5A's approach that has been adopted by the USPSTF to describe such services:

1. **Assess**: Ask about/assess behavioral health risk(s) and factors affecting choice of behavior change goals/methods.
2. **Advise**: Give clear, specific, and personalized behavior change advice, including information about personal health harms and benefits.
3. **Agree**: Collaboratively select appropriate treatment goals and methods based on the patient's interest in and willingness to change the behavior.
4. **Assist**: Using behavior change techniques (self-help and/or counseling), aid the patient in achieving agreed-upon goals by acquiring the skills, confidence, and social/environmental supports for behavior change, supplemented with adjunctive medical treatments when appropriate.
5. **Arrange**: Schedule follow-up contacts (in person or by telephone) to provide ongoing assistance/support and to adjust the treatment plan as needed, including referral to more intensive or specialized treatment.

For the purposes of this decision memorandum, a primary care setting is defined as one in which there is provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community. Emergency departments, inpatient hospital settings, outpatient hospital settings, ambulatory surgical centers, independent diagnostic testing facilities, skilled nursing facilities, inpatient rehabilitation facilities and hospices are not considered primary care settings under this definition.

For the purposes of this proposed decision memorandum a “primary care physician” and “primary care practitioner” will be defined based on two existing sections of the Social Security Act(§1833(u)(6), §1833(x)(2)(A)(i)(I) and §1833(x)(2)(A)(i)(II)).

§1833(u)
(6)Physician Defined.—For purposes of this paragraph, the term “physician” means a physician described in section 1861(r)(1) and the term “primary care physician” means a physician who is identified in the available data as a general practitioner, family practice practitioner, general internist, or obstetrician or gynecologist.

§1833(x)(2)(A)(i)
(I) is a physician (as described in section 1861(r)(1)) who has a primary specialty designation of family medicine, internal medicine, geriatric medicine, or pediatric medicine; or

(II) is a nurse practitioner, clinical nurse specialist, or physician assistant (as those terms are defined in section 1861(aa)(5)).

We are requesting public comments on this proposed determination pursuant to section 1862(l) of the Social Security Act. After considering the public comments, we will make a final determination and issue a final decision memorandum.

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Proposed Decision Memo

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SUBJECT: Proposed Coverage Decision Memorandum for Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse

DATE: July 19, 2011

I. Proposed Decision

The Centers for Medicare and Medicaid Services (CMS) proposes the following:

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We are requesting public comments on this proposed determination pursuant to section 1862(l) of the Social Security Act. After considering the public comments, we will make a final determination and issue a final decision memorandum.

II. Background

The USPSTF Recommendation Statement on "Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse (April 2004) states the following:

- The USPSTF recommends screening and behavioral counseling interventions to reduce alcohol misuse by adults, including pregnant women, in primary care settings. **Grade: B recommendation**.[1]

As discussed in the *Tenth Special Report on Alcohol and Health* to the U.S. Congress (2000), researchers have identified multiple adverse consequences for individuals who misuse alcohol, as well as adverse consequences for their families, friends, co-workers and others whom they encounter. Risk varies widely, but there is generally increased risk of adverse effects to both individuals and society as average alcohol intake increases. One's drinking pattern, such as binge drinking, is important – with risk increasing markedly as blood alcohol concentration rises. Other variables, such as frequency of heavier drinking occasions and drinking to intoxication likewise aid in predicting potential alcohol-related problems, even after controlling for average intake. For individuals, alcohol misuse is linked to diseases such as cancer, liver disease and cardiac disease. Alcohol abuse, for example, leads to inflammation and progressive scarring (cirrhosis) of the liver – a cause of significant morbidity and mortality throughout the world. Women may be more susceptible than men to cumulative effects of alcohol and alcohol-induced liver disease. For society at large, alcohol-related problems also include economic losses from time off work due to illness and injury (automobile crashes, falls and fires), disruption of family and social relationships, mental and emotional problems, plus violence and aggression (domestic violence, child abuse, rape, robbery and assault).[2]

The burden that alcohol misuse consequently places upon the health of populations, and its significant economic consequences, has led to national and international programs seeking to reduce consumption levels and thus reduce a primary cause of avoidable ill health. The impetus for such an approach has been reinforced by epidemiological research which shows that, on a population level, the majority of alcohol-related harm is not due to drinkers with severe alcohol dependence, but is attributable to a much larger group of excessive or hazardous drinkers – whose consumption of alcohol exceeds recommended levels and who experience an increased risk of physical, psychological or social harm to themselves and others.[3]

According to the United States Preventive Services Task Force (USPSTF) Recommendation Statement (2004), alcohol misuse includes risky/hazardous and harmful drinking which place individuals at risk for future problems; and risky or hazardous drinking is defined as > 7 drinks per week or > 3 drinks per occasion for women, and > 14 drinks per week or > 4 drinks per occasion for men. Harmful drinking describes those persons currently experiencing physical, social or psychological harm from alcohol use, but who do not meet criteria for dependence.[4]

In 2005, referencing multiple data sources for definitions of unhealthy alcohol use, Saitz more specifically defined risky use as > 7 standard drinks per week or > 3 drinks per occasion *for women and persons > 65 years of age*, and > 14 standard drinks per week or > 4 drinks per occasion *for men ≤ 65 years of age.* This report included the caveat that the thresholds do not apply to pregnant women for whom the healthiest choice is generally abstinence.[5] Similarly, the 2005 Clinician's Guide from the National Institute of Health's (NIH) National Institute on Alcohol Abuse and Alcoholism (NIAAA) – written for primary care and mental health clinicians – adds to its age-appropriate, maximum drinking limits for healthy adults that clinicians recommend lower limits or abstinence as medically indicated, for example, for patients who take medications that interact with alcohol, have a health condition exacerbated by alcohol, or are pregnant (advise abstinence).[6]

Alcohol intake, however, varies along a spectrum from dependence/alcoholism with severe consequences to moderate/less than risky use which may be beneficial. But what constitutes "moderate" use is dependent upon age, gender, genetic factors and coexisting illnesses.[7] In February 2011, for example, systematic reviews and meta-analyses – funded by the Robert Wood Johnson (RWJ) Foundation, Substance Abuse and Mental Health Services Administration (SAMHSA) and Center for Substance Abuse Treatment (CSAT)[8] – concluded that light to moderate (i.e., less than risky) alcohol consumption (up to one drink or 12.5 grams of alcohol per day for women, and up to two drinks or 25 grams of alcohol per day for men) are associated with a reduced risk of cardiovascular outcomes and favorable changes in cardiovascular biomarkers. There is continuing debate and lingering question about whether such an association is causal.[9],[10]

Based on the USPSTF recommendation, quoted above, our analysis focuses upon screening and brief behavioral counseling services furnished by qualified physicians and other Medicare-recognized practitioners in primary care settings to adults whose patterns of alcohol consumption do not meet criteria for alcohol dependence. Our analysis does not address therapeutic interventions such as pharmacotherapy, combination therapy (counseling and medications), or other intensive alcohol cessation interventions for alcohol dependent or addicted individuals. Self-help materials, telephone calls and web-based counseling are not separately reimbursable by Medicare and are not a part of this analysis.

The scope of this memorandum is limited to the screening and counseling services described, and we are not considering Medicare coverage policy for other treatments of alcohol misuse or any diseases, complications or chronic conditions resulting from alcohol misuse.

III. History of Medicare Coverage

Pursuant to §1861(ddd) of the Social Security Act, CMS may add coverage of "additional preventive services" if certain statutory requirements are met. Our regulations provide:

§410.64 Additional preventive services

(a) Medicare Part B pays for additional preventive services not described in paragraph (1) or (3) of the definition of “preventive services” under §410.2, that identify medical conditions or risk factors for individuals if the Secretary determines through the national coverage determination process (as defined in section 1869(f)(1)(B) of the Act) that these services are all of the following:

(1) Reasonable and necessary for the prevention or early detection of illness or disability.

(2) Recommended with a grade of A or B by the United States Preventive Services Task Force.

(3) Appropriate for individuals entitled to benefits under part A or enrolled under Part B.

(b) In making determinations under paragraph (a) of this section regarding the coverage of a new preventive service, the Secretary may conduct an assessment of the relation between predicted outcomes and the expenditures for such services and may take into account the results of such an assessment in making such national coverage determinations.[11]

IV. Timeline of Recent Activities

February 18, 2011	CMS initiates this national coverage analysis for screening and behavioral counseling in primary care to reduce alcohol misuse.
March 20, 2011	Initial 30-day public comment period closes.

V. FDA Status

Counseling services do not generally fall under the purview of the FDA.

VI. General Methodological Principles

When making national coverage determinations concerning additional preventive services, CMS applies the statutory criteria in §1861(ddd)(1) of the Social Security Act and evaluates relevant clinical evidence to determine whether or not the service is reasonable and necessary for the prevention or early detection of illness or disability, is recommended with a grade of A or B by the USPSTF, and is appropriate for individuals entitled to benefits under part A or enrolled under Part B of the Medicare program.

Public comments sometimes cite published clinical evidence and give CMS useful information. Public comments that give information on unpublished evidence such as results of individual practitioners or patients are less rigorous and therefore less useful for making a coverage determination. Public comments that contain personal health information will not be made available to the public. CMS uses the initial public comments to inform its proposed decision. CMS responds in detail to the public comments on a proposed decision when issuing the final decision memorandum.

VII. Evidence

A. Introduction

Consistent with §1861(ddd)(1)(A) and 42 CFR 410.64(a)(1), additional preventive services must be reasonable and necessary for the prevention or early detection of illness or disability. With respect to evaluating whether screening tests conducted on asymptomatic individuals are reasonable and necessary, the analytic framework involves consideration of different factors compared to either diagnostic tests or therapeutic interventions. Evaluation of screening tests has been largely standardized in the medical and scientific communities, and the "value of a screening test may be assessed according to the following criteria:

i. *Simplicity*. In many screening programmes more than one test is used to detect one disease, and in a multiphasic programme the individual will be subjected to a number of tests within a short space of time. It is therefore essential that the tests used should be easy to administer and should be capable of use by para-medical and other personnel.
ii. *Acceptability*. As screening is in most instances voluntary and a high rate of co-operation is necessary in an efficient screening programme, it is important that tests should be acceptable to the subjects.
iii. *Accuracy*. The test should give a true measurement of the attribute under investigation.

iv. *Cost*. The expense of screening should be considered in relation to the benefits resulting from the early detection of disease, i.e., the severity of the disease, the advantages of treatment at an early stage and the probability of cure.
v. *Precision (sometimes called repeatability)*. The test should give consistent results in repeated trials.
vi. *Sensitivity*. This may be defined as the ability of the test to give a positive finding when the individual screened has the disease or abnormality under investigation.
vii. *Specificity*. This may be defined as the ability of the test to give a negative finding when the individual screened does not have the disease or abnormality under investigation."[12]

As Cochrane and Holland (1971) further noted, evidence on health outcomes, i.e., "evidence that screening can alter the natural history of disease in a significant proportion of those screened", is important in the consideration of screening tests since individuals are asymptomatic and "the practitioner initiates screening procedures".

1. Screening Tests for Alcohol Misuse

Screening tests are designed to identify individuals experiencing an alcohol use problem. In order to evaluate the large number of available screening tools, including the commonly used questionnaires listed below, readers are referred to "Self-Report Screening for Alcohol Problems Among Adults" and "Alcohol-Screening Instruments for Pregnant Women".[13],[14] These two detailed publications by the NIAAA define and assess alcohol screening tools on a variety of dimensions including test sensitivity, specificity, predictive value, likelihood ratios and receiver operating curves, and which also provide tables describing the screening instrument's target population, normed groups, number of items and subscales, format options, time to administer, plus the availability of psychometric data on test reliability (test-retest, split-half, internal consistency) and validity (content, criterion and construct).

Commonly Used Questionnaires for Adults[15,16]

- AUDIT (Alcohol Use Disorders Identification Test)

  The AUDIT, a 10-item screening questionnaire with 3 questions on the amount and frequency of drinking, 3 questions on alcohol dependence, and 4 on problems caused by alcohol, was developed by the World Health Organization (WHO) to identify persons whose alcohol consumption has become hazardous or harmful to their health.[17,18]

- CAGE (Cut down, Annoyed, Guilt, Eye-opener)

The CAGE, a 4-item screening tool, is a very brief (less than one minute), relatively nonconfrontational questionnaire for detection of alcoholism usually directed as “Have you ever…?” but may be focused to delineate past or present.[19]

- MAST (Michigan Alcohol Screening Test)

The MAST, a 25-item screening questionnaire designed to provide rapid and effective screening for lifetime alcohol-related problems and alcoholism, has been used in a variety of settings with varied populations. A 13-item Short MAST (SMAST) plus a geriatric version (MAST-G) and a short geriatric version (SMAST-G) are also available.[20]

- AUDIT-C (AUDIT-Consumption)

The AUDIT-C, a three-item screening questionnaire (the first three questions of the AUDIT), was first validated for identification of alcohol misuse in patients from three Veterans Affairs (VA) general medical clinics[21] and was subsequently validated as a screening questionnaire for alcohol misuse or alcohol use disorders in a large ethnically diverse U.S. primary care sample.[22]

Additional Commonly Used Questionnaires for Pregnant Women[23,24]

- T-ACE (Tolerance – Annoyed, Cut down, Eye-opener)

The T-ACE, a 4-item screening questionnaire based on the CAGE, identifies a range of use, including lifetime use and prenatal use.[25] T-ACE, the first validated sensitive screen for risk drinking (defined as alcohol consumption of 1 ounce or more per day) developed for use in obstetric-gynecologic practices, has subsequently demonstrated acceptability and accuracy in identifying alcohol-use levels in diverse obstetric populations.[26]

- TWEAK (Tolerance, Worried, Eye-opener, Amnesia, K/Cut down)

The TWEAK, a five-item screening tool that includes questions from the MAST, CAGE, and T-ACE, was developed to screen for risk drinking during pregnancy.[27]

B. United States Preventive Services Task Force (USPSTF)

The USPSTF Recommendation Statement on "Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse (April 2004) states the following:

- The USPSTF recommends screening and behavioral counseling interventions to reduce alcohol misuse by adults, including pregnant women, in primary care settings. **Grade: B recommendation**.[28]

There is no gold standard for screening hazardous drinking behavior, and the USPSTF did not recommend specific screening tests for alcohol misuse. According to the USPSTF, "clinicians can choose screening strategies that are appropriate for their clinical population and setting", but "the optimal interval for screening and intervention is unknown."[29]

Importantly, the inclusion criteria for the systematic evidence review forming the basis for the USPSTF recommendations (Whitlock, *et al.* 2004) required that all studies had to be conducted in a *primary care setting* where, as defined by the Institute of Medicine (1996), "*primary care* is the provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community." Excluded were other non-primary clinical settings, such as emergency departments and hospitals, specialty addiction treatment settings, behavioral health departments, and schools or community agencies without health clinics, to maximize the applicability of the review findings to primary care.[30]

"Effective interventions to reduce alcohol misuse include an initial counseling session of about 15 minutes, feedback, advice and goal-setting" and "most also delivered further assistance and follow-up" – elements which are consistent with the **5As** approach[31] to describing behavioral counseling interventions in clinical care that have been adopted by the USPSTF:

1. **Assess**: Ask about/assess behavioral health risk(s) and factors affecting choice of behavior change goals/methods.
2. **Advise**: Give clear, specific, and personalized behavior change advice, including information about personal health harms and benefits.
3. **Agree**: Collaboratively select appropriate treatment goals and methods based on the patient's interest in and willingness to change the behavior.
4. **Assist**: Using behavior change techniques (self-help and/or counseling), aid the patient in achieving agreed-upon goals by acquiring the skills, confidence, and social/environmental supports for behavior change, supplemented with adjunctive medical treatments when appropriate.
5. **Arrange**: Schedule follow-up contacts (in person or by telephone) to provide ongoing assistance/support and to adjust the treatment plan as needed, including referral to more intensive or specialized treatment.

USPSTF Grade Definitions Prior to May 2007

The definitions below (of USPSTF grades and quality of evidence ratings) were in use prior to the update and apply to recommendations voted on by the USPSTF prior to May 2007.

A – Strongly Recommended: The USPSTF strongly recommends that clinicians provide [the service] to eligible patients. *The USPSTF found good evidence that [the service] improves important health outcomes and concludes that benefits substantially outweigh harms*.

B – Recommended: The USPSTF recommends that clinicians provide [the service] to eligible patients. *The USPSTF found at least fair evidence that [the service] improves important health outcomes and concludes that benefits outweigh harms*.

C – No Recommendation: The USPSTF makes no recommendation for or against routine provision of [the service]. *The USPSTF found at least fair evidence that [the service] can improve health outcomes but concludes that the balance of benefits and harms is too close to justify a general recommendation*.

D – Not Recommended: The USPSTF recommends against routinely providing [the service] to asymptomatic patients. *The USPSTF found at least fair evidence that [the service] is ineffective or that harms outweigh benefits*.

I – Insufficient Evidence to Make a Recommendation: The USPSTF concludes that the evidence is insufficient to recommend for or against routinely providing [the service]. *Evidence that the [service] is effective is lacking, of poor quality, or conflicting and the balance of benefits and harms cannot be determined*.

Quality of Evidence

The USPSTF [prior to May 2007] graded the quality of the overall evidence for a service on a 3-point scale (good, fair, poor):

Good: Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes.

Fair: Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies, generalizability to routine practice, or indirect nature of the evidence on health outcomes.

Poor: Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.

C. Literature Search

In addition to the prerequisite USPSTF recommendations, CMS must consider not only whether an additional preventive service is reasonable and necessary for the prevention or early detection of illness or disability, but whether the service is appropriate for individuals entitled to benefits under part A or enrolled under part B of the Medicare program.

To facilitate these determinations, we searched PubMed from 2001 to 2011 for original research studies, systematic reviews and clinical guidelines for screening and behavioral counseling in primary care to reduce alcohol abuse, as well as disparities in the provision or receipt of these services, in older or elderly adults plus pregnant patients (to include disabled female Medicare beneficiaries < 65 years of age). Studies of cost and cost-effectiveness were also searched, as §1861(ddd)(2) expressly authorizes the agency to "conduct an assessment of the relation between predicted outcomes and the expenditures for such services". Studies must have been published in peer-reviewed English language journals, and abstracts were excluded.

Using these general parameters, CMS identified three clinical guidelines and 14 research studies, which included nine reviews and/or meta-analyses plus one randomized controlled trial (RCT).

D. Discussion of evidence reviewed

1. Evidence Questions

Our discussion focuses upon the adequacy of the evidence to draw conclusions about the risks and benefits of screening and behavioral counseling interventions in primary care to reduce alcohol abuse for Medicare patients. CMS analyzed the following questions:

- *Is the evidence sufficient to determine that screening and behavioral counseling interventions in primary care to reduce alcohol misuse is recommended with a grade of A or B by the USPSTF for any indications?*
- *Is the evidence sufficient to determine that screening and behavioral counseling interventions in primary care to reduce alcohol misuse is reasonable and necessary for the prevention or early detection of illness or disability?*
- *Is the evidence sufficient to determine that screening and behavioral counseling interventions in primary care to reduce alcohol misuse is appropriate for Medicare beneficiaries?*

2. External technology assessments and systematic reviews

Health Outcomes in General Adult Population

Kaner, *et al.* (2007 Cochrane Review)

Noting that excessive drinking contributes significantly to social, physical and psychological problems, and that its hidden effects include increased levels of violence, accidents and suicide, Kaner and colleagues assessed brief intervention to reduce alcohol consumption delivered in general practice settings. Selection criteria included randomized controlled trials (RCTs) from 1966-2006 of patients routinely presenting to primary care not specifically for alcohol treatment, and for brief intervention of up to four sessions. Trials variably used established screening tools such as CAGE, AUDIT or MAST, or combinations of these tools to increase the likelihood of picking up relevant participants. Number of sessions ranged from one to five, sessions varied from one to 50 minutes, total intervention time ranged from a mean of 7.5 to 60 minutes, and administering professionals were general practitioners, nurse practitioners or psychologists. Only data for entire trials were analyzed, and excluded reports were of subgroups reported in other references, including an elderly subgroup (Gordon 2003) from the Early Lifestyle Modification trial. Of the total participants (N = 7,619; mean age = 43 years of age), about 70% were men; and while ethnicity was poorly reported, in those trials which did report it, about 70% of participants were white. On entering the trials, participants consumed, on average, about 310 grams of alcohol (over 30 standard drinks) per week, but this varied between trials from about 90 to 460 grams per week.[32]

Although there was substantial heterogeneity between trials, this meta-analysis of 22 RCTs showed that participants receiving brief intervention had lower alcohol consumption than controls after follow-up of at least one year (mean difference: -38 grams or 4-5 units/week). Subgroup analysis of eight studies (N = 2,307) confirmed benefit of brief intervention in men (mean difference: -57 grams/week), but not in women (mean difference: -10 grams/week). Meta-regression showed little evidence of greater reduction in alcohol consumption with longer treatment exposure, and extended intervention was associated with a non-significantly greater reduction in consumption than brief intervention (mean difference = -28 grams/week). Kaner, *et al.* concluded that, while brief interventions overall lowered alcohol consumption, when data were available by gender, the effect was clear in men but not in women, which may in part be due to low statistical power as trials reporting outcomes from women only enrolled a total of 499 participants. The authors also stated that longer duration of counseling likely has little additional beneficial effect; and the lack of difference in outcomes between efficacy and effectiveness trials suggests that the current literature is relevant to routine primary care, i.e., the benefits of brief alcohol intervention are similar in normal clinical settings and in research settings with greater resources.[33]

Bertholet, *et al.* (2005)

Examining any possible gender differences, Bertholet and colleagues (2005) also evaluated the efficacy of brief alcohol intervention (BAI) in patients attending primary care facilities who were not specifically seeking help for alcohol-related problems. Criteria included RCTs conducted in outpatient primary care centers reporting at least one outcome related to alcohol consumption. Studies performed in a hospital or emergency department were not eligible, and studies selecting patients by registers/patient lists or specifically convening persons for screening purposes were also excluded. Nineteen trials (N = 5639) were identified, and a meta-analysis was performed of studies reporting alcohol consumption at six or 12 months follow-up. Seventeen trials measured alcohol consumption, of which eight reported a significant effect of intervention. Intention-to-treat (ITT) analysis showed a mean pooled difference of −38 grams of ethanol (approximately four drinks) per week favoring brief alcohol intervention, and only a small difference in effect size was found between men and women. Among seven trials reporting significant improvement in BAI groups compared to controls, all but one reported an intervention lasting between 5-15 minutes. Bertholet, *et al.* consequently stated that BAI from 5-15 minutes, accompanied by written material and an opportunity for the patient to schedule a follow-up visit, has potential to significantly reduce alcohol consumption compared to no BAI, usual care, or less than five minutes of intervention; and the authors concluded that brief alcohol intervention is effective for both men and women to reduce consumption at six and 12 months.[34]

Ballesteros, *et al.* (2004)

Ballesteros and colleagues similarly performed a meta-analysis of studies conducted in primary health care settings with six to 12 months follow-up that reported results separately by gender. Outcome measures were quantity of typical weekly alcohol consumption and frequency of drinkers who reported consumption below hazardous levels after intervention. Meta-analysis of seven studies showed standardized effect sizes for reduction of alcohol consumption were similar in men (d = -0.25) and women (d = -0.26), and differences in odds ratios (OR) between genders for frequency of individuals who drank below harmful levels was also negligible (four studies; OR for men = 2.32; OR for women = 2.31). Ballesteros, *et al.* concluded that their meta-analysis supported equality of outcomes among men and women achieved by brief interventions for hazardous alcohol consumption in primary care settings.[35]

Mokdad, *et al.* (2004)

Updating a 1993 seminal article[36] which established that modifiable behavioral risk factors are the leading causes of mortality in the U.S., Mokdad and colleagues searched MEDLINE from 1980-2002 for epidemiological, clinical and laboratory studies linking risk behaviors and mortality. Prevalence and relative risk were identified, and 2000 mortality data reported to the Centers for Disease Control and Prevention was used to identify causes and number of deaths. Results showed the three leading causes of death in 2000 were tobacco (435,000 deaths; 18.1% of U.S. deaths), poor diet and physical inactivity (365,000 deaths; 15.2%) [corrected], and alcohol consumption (85,000 deaths; 3.5%). Mokdad, *et al.* stated about half of the deaths in the U.S. were attributable to a limited number of largely preventable behaviors and exposures, and concluded that – along with escalating health care costs and aging population – their findings argue persuasively for the urgent need to establish a more preventive orientation in U.S. health care and public health systems.[37]

Health Outcomes in Pregnant Women

Bailey and Sokol (2008)

Bailey and Sokol reviewed the linkage between maternal alcohol consumption in pregnancy to classic fetal alcohol syndrome (FAS) – which includes prenatal and postnatal growth restriction, central nervous system and neurodevelopmental delays, plus facial dysmorphology of affected children, as well as fetal alcohol spectrum disorder (FASD) – which characterizes a spectrum of adverse outcomes associated with prenatal alcohol exposure. The authors described that even absent diagnosable FAS, maternal alcohol consumption increases the risk of poor physical, cognitive and behavioral outcomes in exposed children, and that prenatal alcohol exposure is a strong predictor of both low birth weight and preterm birth – which are leading proximate causes of neonatal morbidity and mortality in the U.S., as well as the strongest biologic predictors of immediate and long-term developmental outcomes.

Moreover, children exposed to alcohol prenatally demonstrate delays in motor development, including both fine and gross motor dysfunctions, plus impairments in visual motor integration. And prenatal alcohol exposure is also linked to cognitive deficits – including slowed mental processing, problems with receptive language function, delayed reading and planning ability, decreased academic achievement and increased learning problems, in addition to behavioral deficits – most notably overactivity and attention deficits. Other critical findings included that, although most prenatal care providers ask women about alcohol use, validated screening tools are infrequently employed, as well as that research has demonstrated that current screening methods and intervention techniques are effective in identifying and reducing drinking during pregnancy. Noting that there is no known threshold of safety for alcohol use during pregnancy, that every pregnancy is different, that drinking alcohol may hurt one baby more than another because of differing susceptibilities, and that the most noticeable effects of FASD have been seen in children born to women > 30 years old at delivery, Bailey and Sokol concluded that implementing universal alcohol screening and appropriate intervention for pregnancy alcohol use should be a priority for providers of prenatal care, as these efforts could substantially improve pregnancy, birth, and children's long-term developmental outcomes.[38]

Nilsen (2009)

Nilsen described brief alcohol interventions, summarized the evidence base, and addressed opportunities for providing alcohol interventions for pregnant women in antenatal care. Findings included that brief intervention has emerged as a promising approach for providing early intervention before or soon after onset of alcohol-related problems, and that there is convincing evidence for efficacy and effectiveness of brief intervention in various healthcare settings. Results of four brief intervention trials conducted with pregnant women (Handmaker 1999, Chang 1999, Chang 2005 and O'Connor 2007) are also consistent with the broader literature on brief intervention. However, while brief interventions were effective in reducing alcohol consumption, control group participants likewise reduced alcohol consumption to the degree that statistically significant differences between the groups were generally difficult to detect. Nilsen nonetheless noted that pregnant women are believed to be highly motivated to reduce their alcohol intake, and that the contextual change provided by pregnancy provides an opportunity to break habitual drinking behaviour. The author concluded that there is empirical and theoretical support for providing brief intervention in antenatal care to achieve reduced or no alcohol consumption during pregnancy.[39]

Cheng, *et al.* (2011)

Cheng and colleagues estimated the prevalence of prenatal alcohol consumption and the extent of provider screening and discussion about alcohol use during pregnancy. Data were obtained from a stratified random sample of 12,611 mothers from Maryland who delivered live infants from 2001 to 2008 and completed the Maryland Pregnancy Risk Assessment Monitoring System survey. Results showed that nearly 8% (95% CI 7.1-8.4) of mothers from Maryland reported alcohol consumption during the last three months of pregnancy. Nineteen percent (CI 17.6-21.0) of mothers reported that their prenatal care provider did not ask if they were drinking alcoholic beverages, and 30% (CI 28.3-30.8) of mothers reported that a healthcare provider did not counsel them on how drinking alcohol could affect their baby.

Disparities were present among women who reported alcohol use during pregnancy, as well as among populations counseled about effects of prenatal alcohol exposure and screened for alcohol use. Self-reported alcohol use during the last three months of pregnancy was most prevalent ($P < 0.01$) among women who were 35 years of age or older (13.4%, CI 12.4-14.4), college graduates (11.4%, CI 10.2-12.6), non-Hispanic white race and ethnicity (10.9%, CI 9.8-11.9), not enrolled in Medicaid for delivery (9.4%, CI 8.5-10.2), married (9.3%, CI 8.5-10.2), and used private physicians for their prenatal care (8.1%, CI 7.4-8.9). Cheng, *et al.* concluded that, despite the substantial number of women who continue to drink alcohol during pregnancy, healthcare providers do not routinely assess alcohol consumption or counsel all women about its harmful effects. The authors also noted that counseling was least prevalent among those groups of women with the highest rates for drinking, and that provider alcohol assessment should be promoted as a regular part of prenatal care.[40]

Cost-Effectiveness

Solberg, *et al.* (2008)

Solberg and colleagues performed a systematic literature review from 1992-2004 to identify relevant randomized controlled trials (RCTs) and cost-effectiveness studies, and estimated health impact and cost effectiveness of regular screening for alcohol misuse by brief instruments such as the CAGE and AUDIT questionnaires followed by evaluation of initial positives and brief counseling of true positives. Health impact was estimated by the clinically preventable burden (CPB) – defined as the burden of disease prevented by the service when delivered regularly over the lifetime of a birth cohort of 4,000,000 individuals – which was calculated as the product of effectiveness times the alcohol-attributable fraction of both mortality and morbidity (measured in quality-adjusted life years (QALYs)), for all relevant conditions. Cost-effectiveness of alcohol screening and counseling from both societal and health-system perspectives was estimated for a 10 minute office visit, and the ranges over which model parameters were explored in sensitivity analyses were presented in Table 1 in the Solberg review.

The base case for "portion of 10 minute office visit for screen" was assumed to be 10%, with a range for sensitivity analysis of 5% to 20%. The base case for "screens per year among ages 18-54" was 1.0 (annually), with a range of 0.5 to 2; and the base case for "screens per year among ages 55+" was 0.5 (biennially or every two years), with a range from 0.2 to 1.0 (annually).

Results showed that the calculated CPB was 176,000 QALYs saved over the lifetime of a birth cohort of 4,000,000, with sensitivity analysis ranging from -43% to +94% (primarily due to variation in estimates of effectiveness). Screening and brief counseling was cost-saving from the societal perspective and had a cost-effectiveness ratio of $1755/QALY saved from the health-system perspective.[41] Solberg and colleagues concluded that from both societal and health-system perspectives the service is very cost-effective and may be cost saving – making alcohol screening and counseling one of the highest-ranking preventive services among 25 effective services evaluated using standardized methods (see next analysis by Maciosek). Solberg's review, completed in 2005, provided information on which that ranking was based and was the first cost-utility analysis of alcohol screening and brief intervention.[42]

Maciosek, *et al.* (2006)

Since it is difficult to ascertain which preventive services are most important to focus on with limited time or resources, Maciosek and colleagues conducted a systematic review and analysis to produce comparable estimates of relative health impact and cost- effectiveness for services considered effective by the USPSTF. To aid in prioritization, the National Commission on Prevention Priorities – created by the Partnership for Prevention with funding from the Centers for Disease Control and Prevention and the Agency for Healthcare Research and Quality – utilized new preventive service recommendations up to December 2004, improved methods, plus more complete and recent data and evidence since the first ranking of prevention priorities in 2001. Each preventive service received one to five points on clinically preventable burden (CPB) and cost-effectiveness, for a total score ranging from two to ten. Priorities for improving delivery rates were established by comparing the ranking with what is known of current delivery rates nationally. Results showed the three highest-ranking services were discussing aspirin use with high-risk adults, immunizing children, plus tobacco-use screening and brief intervention. Additional high-ranking services included problem drinking screening and brief counseling (score of 8) to identify individuals whose alcohol use places them at increased risk and provide brief counseling with follow-up. Maciosek and colleagues' study identified that alcohol screening and counseling is one of the most valuable clinical preventive services that can be offered in medical practice.

3. Internal technology assessment

Fleming, *et al.*(2002)

Fleming and colleagues reported the 48-month efficacy and benefit-cost analysis of Project TrEAT (Trial for Early Alcohol Treatment), an RCT of brief physician advice for treatment of problem drinking. This study was conducted in the offices of 64 community-based primary care physicians from 17 clinics in 10 southern Wisconsin counties. In Project TrEAT, all patients between 18 to 65 years of age who entered their physician's offices for routine care were asked to complete a self-administered health screening questionnaire containing parallel questions on smoking, exercise, weight concerns, and alcohol use; and those patients who screened positive for at-risk alcohol consumption were invited to participate in a face-to-face assessment interview with a study researcher. Primary exclusion criteria were formal alcohol treatment within the past year, history of alcohol withdrawal, pregnancy, and suicide ideation; and informed consent was obtained both at the initial screening and prior to the face-to-face baseline assessment interview. Four hundred eighty-two men and 292 women who met all criteria and agreed to participate were randomized to a usual care control group (N = 382) or a brief intervention group (N = 392) consisting of two scripted 15-min sessions scheduled one month apart and two scripted five-minute follow-up calls from an office nurse. Intervention components included a review of normative drinking, patient-specific alcohol effects, a worksheet on drinking cues, drinking diary cards, and a drinking agreement in the form of a prescription.

Results showed that subjects in the treatment group exhibited significant reductions ($p < 0.01$) in seven-day alcohol use, number of binge drinking episodes, and frequency of excessive drinking as compared with the control group. The effect occurred within six months of the intervention and was maintained over the 48-month follow-up period. Regarding health care utilization, the treatment group experienced 37% fewer days of hospitalization (420 versus 664, $p < 0.05$) and 20% fewer emergency department visits (302 versus 376, $p < 0.08$). Subjects from the usual care group experienced two motor vehicle crash fatalities and 55% more crashes with nonfatal injuries (31 versus 20); and the usual care group also incurred 46% more arrests for legal events (41 versus 28), including a significant difference in arrests for controlled substance or liquor violations (11 versus 2, $p < 0.05$). Seven subjects in the control group and three in the treatment group died during the follow-up period, representing a statistically significant difference in mortality at 36 months ($p < 0.05$) but not at 48 months. The authors stated that benefit-cost analysis suggests a $43,000 reduction in future health care costs for every $10,000 invested in early intervention, and that the benefit-cost ratio increases when including the societal benefits of fewer motor vehicle events and crimes. Fleming, *et al.* concluded that the long-term follow-up of Project TrEAT provided evidence that brief physician advice is associated with sustained reductions in alcohol use, health care utilization, motor vehicle events and associated costs.[43]

Gordon, *et al.* (2003)

In a post-hoc analysis of the Early Lifestyle Modification (ELM) trial, Gordon and colleagues evaluated whether brief interventions (BI), motivational enhancement (ME) and brief advice (BA) reduced alcohol consumption among hazardous alcohol drinking elderly ≥ 65 years of age, and whether such elderly individuals responded similarly to younger populations. In 12 primary care offices from October 1995 to December 1997, the ELM study screened 13,438 patients, of whom 2702 (20%) were elderly. Elderly were generally the "young-old" (76% between 66-75 years of age); 23% were between 76-85 years of age; and 2% were > 85 years of age. Overall, 180 elderly (7%) met either one or both criteria (AUDIT or quantity-frequency) for hazardous drinking, but 75% of the elderly (and similarly the nonelderly) who were identified as hazardous drinkers declined to participate. Relevant exclusion criteria for the elderly were either treatment for an alcohol problem in the previous year or malignancy; and of the eligible elderly, 45 (25%) agreed to participate and were randomized (12 elderly to Standard of care (SC), 15 to BA, and 18 to ME).

There were no significant differences in demographic variables (age, race, education) between elderly assigned to the three different treatment arms. At baseline, the elderly abstained fewer days than the younger cohort and drank more alcohol per month. That is, while the elderly drank on average one less drink per drinking day (4.1 versus 5.0 drinks) compared to the non-elderly, they had fewer days abstinent per month (11.6 days versus 17.1 days) and more often consumed one to six standard drinks per day (9.3 days versus 5.8 days) compared to non-elderly participants. Consequently, at baseline, the elderly drank more alcohol per month. During the one year follow-up, results showed that the elderly in the ME, BA and SC intervention arms increased the number of days abstained, decreased number of drinks per day, and reduced number of total days per month drinking. Similar to the nonelderly, while there was significant reduction in consumption measures over time, there were trends toward decreases (but no significant differences) in alcohol consumption measures in the ME and BA treatment arms compared to SC. Gordon, *et al.* concluded that hazardous alcohol consumption in the elderly is common and that brief alcohol interventions reduce consumption in the elderly similar to younger populations.[44]

Screening Tools

Frank, *et al.* (2008)

Noting that AUDIT-C was validated in predominantly White populations, Frank and colleagues conducted a cross-sectional interview validation study to evaluate the validity of the AUDIT-C among primary care patients from predominant racial/ethnic subgroups within the U.S., i.e., White, African American and Hispanic. A total of 1,445 eligible adult family medicine patients were randomly sampled for recruitment, with oversampling of minority and female patients. 90% of eligible patients (N = 1,292) agreed to participate, including 906 women and 386 men. Description of measurements included that race/ethnicity was self-reported. Areas under the receiver operating curve (AuROCs) evaluated overall AUDIT-C performance in the three racial/ethnic groups compared to diagnostic interviews for alcohol misuse, and AUDIT-C sensitivities and specificities at recommended screening thresholds were compared across racial/ethnic groups.

Main results showed that the AuROCs were greater than 0.85 in all three groups, with no significant differences across racial/ethnic groups in men (P = 0.43) or women (P = 0.12). At previously recommended cut points for detecting alcohol misuse (≥3 points for women and ≥4 points for men), there were statistically significant differences by race in AUDIT-C sensitivities but not specificities. In women, the sensitivity was higher in Hispanic (85%) than in African-American (67%; P = 0.03) or White (70%; P = 0.04) women. In men, the sensitivity was higher in White (95%) than in African-American men (76%; P = 0.01), but exhibited no significant difference from Hispanic men (85%; P = 0.11). Frank, *et al.* concluded that the overall performance of the AUDIT-C was excellent in all three racial/ethnic groups as reflected by high AuROCs. At the recommended cut points, there were significant differences in the AUDIT-C's sensitivity[45] but not in its specificity[46] across the three racial/ethnic groups.[47]

Aalto, *et al.* (2010)

Noting that performance of the AUDIT in screening for heavy drinking among the elderly was unsatisfactory, Aalto and colleagues sought to determine whether tailoring the cut point improved performance of the AUDIT and its derivatives. From a stratified random sample of 804 persons aged 65-74 years, 517 subjects (64.3%) completed the AUDIT and the Timeline Follow-Back (TLFB) interview regarding alcohol consumption. A subject was defined as a heavy drinker if consumption of ≥8 drinks on average in a week or ≥4 drinks at least in one day during the prior 28 days was reported. Combinations in which both sensitivity and specificity are ≥ 0.80 were defined as optimal, and an elderly specific AUDIT-3 is a modification (designed for this study) in which the binge drinking threshold is ≥4 drinks. Results showed that based on the TLFB, 118 subjects (22.8%) were heavy drinkers. The areas under receiving operating characteristics curves (AUROCs) were equivalent (≥ 0.898) for all questionnaires. Using the standard cut point of ≥8 for the AUDIT, sensitivity was 0.48. Lowering the cut point to ≥5 led to both sensitivity and specificity > 0.85, and the optimal cut point of the AUDIT-C was ≥4. Derivatives, including the AUDIT-QF, AUDIT-3 and elderly specific AUDIT-3, did not provide optimal combinations of sensitivity and specificity with any cut point. Aalto, *et al.* concluded that the AUDIT and AUDIT-C are accurate in screening for heavy drinking among the elderly aged 65-74 years if the cut points are tailored to this age group.[48]

Bradley, *et al.* (2011)

Acknowledging that little is known about the performance of alcohol screening questionnaires administered in clinical settings, Bradley and colleagues compared results of alcohol screening conducted as part of routine outpatient clinical care in the Veterans Affairs (VA) Health Care System to results on the same alcohol screening questionnaire (the AUDIT-C) completed on a mailed survey within 90 days in order to identify factors associated with discordant screening results. In this cross sectional study, participants represented a national sample of 6,861 VA outpatients from 2007 to 2008 – including 17% women due to oversampling, but predominately older, White men (2158 [31%] of patients 60-69 years of age and 2546 [37%] of patients ≥ 70 years of age) – who completed the AUDIT-C alcohol screening questionnaire on mailed surveys (survey screen) within 90 days of having AUDIT-C screening documented in their medical records (clinical screen). Alcohol screening results were considered discordant if the patients screened positive (AUDIT-C ≥ 5) on either the clinical or survey screen but not both; and multivariable logistic regression estimated the prevalence of discordance in different patient subgroups based on demographic and clinical characteristics, VA network and temporal factors such as the order of screens.

Results showed that whereas 11.1% (95% CI 10.4-11.9%) of patients screened positive for unhealthy alcohol use on the survey screen, only 5.7% (5.1- 6.2%) screened positive on the clinical screen. Of 765 patients who screened positive on the survey screen, 61.2% (57.7-64.6%) had discordant results on the clinical screen, contrasted with 1.5% (1.2-1.8%) of 6096 patients who screened negative on the survey screen. Additionally, among patients whose clinical screens indicated no alcohol use in the past year (AUDIT-C score = 0), 21.9% reported drinking on survey screens; but among those whose survey screens indicated no past-year alcohol use, 8.7% had clinical screens indicating past-year drinking. In multivariable analyses, discordance was significantly increased among Black patients compared with White, and among patients who had a positive survey AUDIT-C screen or who received care at 4 of 21 VA networks. Bradley, *et al.* concluded that mandating use of a validated alcohol screening tool does not, in and of itself, ensure high quality screening; and the authors suggested that the quality of clinical alcohol screening should be monitored, even when well-validated screening questionnaires are used.

4. Medicare Evidence Development & Coverage Advisory Committee (MEDCAC)

CMS did not hold a MEDCAC meeting on this topic.

5. Evidence-Based Clinical Guidelines

United States Preventive Services Task Force (USPSTF) 2004 *(see Section VII.B. above)*

National Institute on Alcohol Abuse and Alcoholism (NIAAA) 2005

Written for primary care and mental health clinicians, the updated 2005 Clinician's Guide provided a detailed, four-step approach to help patients who drink too much: 1) ask about alcohol use; 2) assess for alcohol use disorder; 3) advise and assist (brief intervention); and 4) at follow-up: continue support.[49]

For patients who do not screen positive – using, for example, a written self-report such as the AUDIT – the guide's flowchart (Step 1, page 4) outlines that clinicians should:

- Advise staying within these Maximum Drinking Limits:

For healthy *men up to age 65*:

- no more than 4 drinks in a day AND
- no more than 14 drinks in a week

For healthy women (and healthy men over age 65):

- no more than 3 drinks in a day AND
- no more than 7 drinks in a week

•Recommend lower limits or abstinence as medically indicated: e.g., for patients who

- take medications that interact with alcohol
- have a health condition exacerbated by alcohol
- are pregnant (advise abstinence)

•Express openness to talking about alcohol use and any concerns it may raise

•Rescreen annually

Substance Abuse and Mental Health Services Administration (SAMHSA) 2008

In its series of Treatment Improvement Protocols (TIPs), SAMHSA's TIP 26: Substance Abuse Among Older Adults offers practice guidelines for the identification, screening, assessment, and treatment of the elderly for alcohol abuse, and also discusses outcomes and financial, ethical, and legal issues. As described, the TIPS are best practice guidelines for the treatment of substance abuse, provided as a service of the SAMHSA's Center for Substance Abuse Treatment, which draws on the experience and knowledge of clinical, research, and administrative experts.[50]

In Chapter 2 - Alcohol, alcohol abuse and misuse is stated to be the major substance abuse problem among older adults; and this TIP brings together literature on substance abuse and gerontology to recommend best practices for identifying, screening, assessing, and treating alcohol [and prescription drug abuse] for persons age 60 and older. Importantly, the chapter addresses comorbidities and notes that, although alcohol can negatively affect a person of any age, the interaction of age-related physiological changes and the consumption of alcohol can trigger or exacerbate additional serious problems among older adults, including increased risk of hypertension, cardiac arrhythmia, myocardial infarction and cardiomyopathy; increased risk of hemorrhagic stroke; impaired immune system and capability to combat infection and cancer; cirrhosis and other liver diseases; decreased bone density; gastrointestinal bleeding; depression, anxiety and other mental health problems; malnutrition; plus cognitive impairments.[51]

Under “Identification, Screening, and Assessment”, the TIP’s consensus panel also practically recommends that health care providers preface questions about alcohol with a link to a medical condition when screening older people. For example, "I'm wondering if alcohol may be the reason why your diabetes isn't responding as it should," or "Sometimes one prescription drug can affect how well another medication is working. Let's go over the drugs you're taking and see if we can figure this problem out."[52]

6. Professional Society Position Statements

American Academy of Family Physicians (AAFP)

On its website under Brief Alcohol Screening and Intervention in Family Medicine, the AAFP presents the following “Rationale for Screening and Brief Intervention for Alcohol Problems in Primary Care”:

“Alcohol-related problems, which cause substantial morbidity and mortality, are common: 14.8% of U.S. adults have engaged in at least one episode of heavy drinking (> 5 drinks) in the previous 30 days, and 7.4% have a diagnosable past-year alcohol use disorder. They are also treatable. In efficacy trials, brief interventions by primary care physicians helped 40% of hazardous drinkers reduce their drinking to safe levels, compared with 20% in control groups.

Screening for alcohol problems can be accomplished quickly and, for both patients and physicians, comfortably. Many screening instruments have been validated, including the four-question CAGE, the ten-item Alcohol Use Disorders Identification Test [AUDIT], and a single question ("When was the last time you had more than 4 drinks [5 if male] in one day?") In a study comparing the CAGE and the single question, physicians were more likely to use the single question, but there were no other significant differences between those two approaches.

In the successful clinical trials, brief interventions have typically taken two 10 to 15 minute office visits. Integrating them into daily practice is therefore challenging. Primary care office visits are short but face complex agendas. Furthermore, physicians value a patient-centered approach to care which will include a discussion of alcohol only if the patient brings it up (which is uncommon) or there is a clear indication to do so (e.g., intoxication).

The same issues can be raised, for example, with hypertension. Patients with no prior history of hypertension seldom present specifically to discuss it. Primary care practices instead have systems that routinely screen for it. When it's found, the physician and patient briefly discuss it, arrange to gather further information (e.g., home blood pressure measurement, lab studies), and schedule a follow-up visit to address it more fully. The same approach can be used for alcohol problems.

Given the prevalence of alcohol use disorders and their contribution to patient morbidity and mortality, it makes sense for family physicians to screen for this problem.[53]

The AAFP outlines Four Screening Steps in a detailed online format: 1) brief screening; 2) brief assessment; 3) advise and assist – a brief intervention; and 4) arrange a follow-up; and matching the USPSTF's recommendations, "the AAFP *recommends* screening and behavioral counseling interventions to reduce alcohol misuse by adults, including pregnant women, in primary care settings (2004)".[54]

American College of Obstetricians and Gynecologists (ACOG)

The ACOG, in collaboration with the Centers for Disease Control and Prevention, has developed the "Drinking and Reproductive Health: A Fetal Alcohol Spectrum Disorders Prevention Tool Kit". The primary component in the tool kit (available at no charge to women's health care providers) is a CD-ROM that aims to teach women's health care providers how to screen and advise all of their patients of reproductive age about risky drinking and encourage the use of effective contraception among patients who continue to engage in risky drinking. With information on screening, education, and counseling, this publication will help women's health care clinicians prevent Fetal Alcohol Spectrum Disorders (FASD) when they encounter risky drinking, regardless of pregnancy.

The ACOG's "Screening and Intervention Guidelines", outlined within the Clinician's Guide Drinking and Reproductive Health in the Prevention Tool Kit, consist of three simple steps – *Ask about alcohol use, Brief intervention, Follow-up for women who engage in risky drinking* – which have been proven effective in identifying women who drink at risky levels and engage them in changing behavior to reduce their risk for an alcohol-exposed pregnancy.[55]

The Prevention Tool Kit also contains Additional Screening and Intervention Tools, such as the CRAFFT (for use in adolescents), TWEAK and AUDIT-C, which may be used instead of the T-ACE tool when screening women for risky alcohol use.[56]

American Public Health Association (APHA)

The APHA has developed "Alcohol Screening and Brief Intervention: A Guide for Public Health Practitioners", a manual providing background information and practical steps for conducting screening and brief intervention (SBI) in a variety of public health settings, whose purpose is to provide public health professionals, such as health educators and community health workers, with the information, skills, and tools needed to conduct SBI so that they can help at-risk drinkers reduce their alcohol use to a safe amount or stop. According the APHA, brief interventions are counseling sessions that last 5 to 15 minutes; and alcohol screening and brief intervention:

- Is designed for use by service providers who do not specialize in addiction treatment;
- Uses motivational approaches based on how ready the person is to change behavior;
- Gives feedback and suggestions respectfully in the form of useful information, without judgment or accusations; and

- Has been shown by research to be effective in reducing alcohol use and alcohol-related adverse consequences, including injury.[57]

7. Public Comments

During the initial 30-day public comment period (02/18/2011 – 03/20/2011), CMS received 105 timely comments. All 105 comments were generally supportive of CMS adding "Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse" as a Medicare covered service. Five commenters provided citations for published literature to support their comments. CMS reviewed the referenced literature, and some are included in this analysis.

CMS received 45 comments from community-based, state, and/or county organizations; 39 from individuals who were not affiliated with or who did not identify an organization; 12 from hospitals; 7 from academic institutions; and two from professional associations – the American Psychological Association (APA) and the National Association of State Alcohol and Drug Abuse Directors, Inc. (NASADAD).

The comments can be reviewed in their entirety on our website at:

http://www.cms.gov/medicare-coverage-database/details/nca-view-public-comments.aspx?NCAId=249&ExpandComments=n&ver=1&NcaName=Screening+and+Behavioral+Counseling+Interventions+in+Primary+Care+to+Reduce+Alcohol+Misuse&bc=BEAAAAAAEAAA&

VIII. CMS Analysis

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act §1869(f)(1)(B). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Since January 1, 2009, CMS is authorized to cover "additional preventive services" (see Section III above) if certain statutory requirements are met as provided under §1861(ddd) of the Social Security Act. Our regulations at 42 CFR 410.64 provide:

(a) Medicare Part B pays for additional preventive services not described in paragraph (1) or (3) of the definition of "preventive services" under §410.2 that identify medical conditions or risk factors for individuals if the Secretary determines through the national coverage determination process (as defined in section 1869(f)(1)(B) of the Act) that these services are all of the following:

(1) Reasonable and necessary for the prevention or early detection of illness or disability.

(2) Recommended with a grade of A or B by the United State Preventive Services Task Force.

(3) Appropriate for individuals entitled to benefits under part A or enrolled under Part B.

(b) In making determinations under paragraph (a) of this section regarding the coverage of a new preventive service, the Secretary may conduct an assessment of the relation between predicted outcomes and the expenditures for such services and may take into account the results of such an assessment in making such national coverage determinations.[58]

Is the evidence sufficient to determine that screening and behavioral counseling interventions in primary care to reduce alcohol misuse is recommended with a grade of A or B by the USPSTF for any indications?

The USPSTF Recommendation Statement on "Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse (April 2004) states the following:

- The USPSTF recommends screening and behavioral counseling interventions to reduce alcohol misuse by adults, including pregnant women, in primary care settings. **Grade: B recommendation**.[59]

We conclude that screening and behavioral counseling interventions to reduce alcohol misuse is recommended with a grade of B by the USPSTF for Medicare beneficiaries, including pregnant women, in primary care settings.

Is the evidence sufficient to determine that screening and behavioral counseling interventions in primary care to reduce alcohol misuse is reasonable and necessary for the prevention or early detection of illness or disability?

In their seminal 1993 article, McGinnis and Foege labeled the most prominent contributors to mortality in the U.S. (the *actual* causes of death) to be tobacco, diet and activity patterns, and alcohol. While misuse of alcohol accounted for 100,000 deaths each year and estimates of alcohol's death toll ranged from 3-10% of deaths, the authors noted that related health, social and economic consequences of alcohol misuse extended far beyond the mortality tables. Estimates, for example, placed alcohol's contribution in the range of 60-90% of cirrhosis deaths; 40-50% of motor vehicle fatalities; 16-67% of home injuries, drownings, fire fatalities and job injuries; and 3-5% of cancer deaths. Significantly, McGinnis and Foege concluded that:

“There can be no illusions about the difficulty of the challenges in changing the impact these factors have on health status. Of those identified here, the three leading causes of death – tobacco, diet and activity patterns, and alcohol – are all rooted in behavioral choices. Behavioral change is motivated not by knowledge alone, but also by a supportive social environment and the availability of facilitative services…

If the nation is to achieve its full potential for better health, public policy must focus directly and actively on those factors that represent the root determinants of death and disability.”[60]

In fact, brief behavioral counseling has since been shown to decrease alcohol consumption; and the USPSTF found good evidence that screening in primary care settings can accurately identify patients whose levels or patterns of alcohol consumption place them at risk for increased morbidity and mortality. Studies of disease burden and effectiveness of brief counseling do generally include both dependent drinkers and nondependent problem drinkers; and – if dependent individuals are less likely to follow through on a referral – the overall effect of alcohol screening may be even greater than estimated. The USPSTF, for example, found good evidence that brief behavioral counseling interventions with follow-up result in small to moderate reductions in alcohol consumption sustained over six to 12 month periods or longer.[61,62] The USPSTF likewise found some evidence (Fleming, *et al.* 2002) that interventions lead to positive health outcomes four or more years post-intervention, but found limited evidence that screening and counseling reduce alcohol-related morbidity. Nonetheless, while the National Center for Health Statistics notes the leading causes of death in the U.S. are heart disease, cancer and stroke, the top three *actual* causes of death continue to be tobacco, poor diet and physical inactivity, and alcohol consumption.[63]

Notably, Fleming and colleagues’ (2002) four-year efficacy and benefit-cost analysis of the Project TrEAT (Trial for Early Alcohol Treatment) RCT provided evidence that brief physician advice is associated with significant reduction ($p < 0.01$) in alcohol use, the number of binge drinking episodes, and frequency of excessive drinking as compared with the control group, plus reduced health care utilization and alcohol-related motor vehicle events.[64] Additionally, Whitlock, *et al.* (2004) – who systematically reviewed and summarized the evidence for the USPSTF – described in their own separate publication that 6-12 months following good-quality, brief, multicontact behavioral counseling interventions (those with up to 15 minutes of initial contact and at least one follow-up), participants reduced the average number of drinks per week by 13-34% more than controls, and the proportion of participants drinking at moderate or safe levels was 10-19% greater compared to controls.

In 2004, the USPSTF noted that evidence on effectiveness of counseling to reduce alcohol consumption during pregnancy was limited; but studies in the general adult population do show that behavioral counseling interventions are effective among women of childbearing age.[65] Critically, alcohol use in pregnancy remains the leading preventable cause of mental retardation among children in the U.S. The woman’s alcohol use is associated with physical, cognitive and behavioral problems known collectively as fetal alcohol spectrum disorder (FASD). FASD is characterized by a spectrum of serious adverse outcomes extending well beyond the three defining features of prenatal/postnatal growth restriction, central nervous system and neurodevelopmental delays, plus facial malformations of affected infants. Moreover, while maternal alcohol consumption in pregnancy is linked with low birth weight and preterm birth (leading proximate causes of neonatal morbidity and mortality), as many as one out of five pregnant women reportedly did not get screened for alcohol consumption and one out of three did not receive information about the effects of alcohol on their babies.[66,67] But Nilsen (2009) concluded that pregnant women are generally believed to be highly motivated to reduce their alcohol intake, that the contextual change provided by pregnancy provides an opportunity to break habitual drinking behaviour, and that there is empirical support for providing brief intervention in antenatal care to achieve reduced or no alcohol consumption during pregnancy.[68] Similarly, the USPSTF concluded that benefits of behavioral counseling interventions to reduce alcohol misuse by adults, including pregnant women, outweigh any potential harms.[69]

Expanding upon the 2004 USPSTF recommendations, Maciosek, *et al.* (2006) systematically reviewed and developed an updated ranking of all clinical preventive services with fair to good evidence of effectiveness. Problem drinking screening and behavioral counseling placed high on the list, indicating that healthcare systems and policy changes are critical to increase utilization and delivery of screening and behavioral counseling for alcohol misuse. Subsequently, Solberg, *et al.* (2008) examined in considerable detail the effectiveness of counseling needed to obtain various cost-effectiveness thresholds; and at base-case frequencies of 1.0 (annual screening) for adults < 55 years of age and 0.5 (biennial or every two year screening) for adults ≥ 55 years of age at each frequency of service delivery, 10% sustained effectiveness of counseling at changing behavior were needed to achieve cost neutrality from the societal perspective. Solberg and colleagues stated it is clear that screening and brief counseling in primary care for alcohol misuse is one of the highest-ranking preventive services among the effective services evaluated by Maciosek, *et al.* (2006) using standardized methods.

We conclude that the evidence is sufficient to determine that screening and behavioral counseling interventions in primary care to reduce alcohol misuse is reasonable and necessary for the prevention or early detection of illness or disability.

Is the evidence sufficient to determine that screening and behavioral counseling interventions in primary care to reduce alcohol misuse is appropriate for Medicare beneficiaries?

Whitlock, *et al's.* (2004) evidence review did not systematically address performance of alcohol screening tests, and the USPSTF did not recommend specific screening tools. While there is currently no gold standard for screening hazardous drinking behavior, particularly for the group of highly heterogeneous, alcohol misusers in the general elderly population[70,71], there are a number of screening tools commonly used in clinical practice.

Moore*, et al.*(2002), for example, noted that fewer than half (43%) of persons ≥ 55 years old screening positive on either the CAGE or the SMAST-G [short geriatric version of MAST] screened positive on both questionnaires – suggesting that these instruments may be capturing different aspects of unsafe drinking.[72] Utilizing another common screening measure, Gordon, *et al.* (2003) stated that the AUDIT "performs well in elder populations and may be particularly good for identifying older people for therapy interventions as, unlike other measures, the AUDIT is specific for current drinking behavior and present risks for alcohol use-related harm."[73] To the contrary, Beullens, *et al.* (2004) believe that while the MAST-G [geriatric] and especially the CAGE appear appropriate, the two questions of Cyr and Wartman, the AUDIT and the MAST do not appear appropriate in screening for alcohol abuse and dependence in elderly people in a clinical environment.[74] Malet, *et al.* (2009), however, raised additional questions regarding the CAGE questionnaire [which was designed primarily to detect dependence], including its mediocre, gender-related performance in men and women over 65 years of age.[75]

Most recently, Aalto, *et al.* (2010) concluded that – while the AUDIT-QF (the two first questions regarding quantity consumed and frequency of drinking), the AUDIT-3 (only the third question from the original AUDIT) and an elderly specific AUDIT-3 (with an lower elderly specific binge drinking limit) developed for the Aalto study did not provide optimal combinations of sensitivity and specificity with any cut point – the AUDIT and the AUDIT-C (the first three questions of the AUDIT) are accurate for screening heavy drinking among elderly individuals aged 65-74 years if the cut points are tailored to this age group.[76] In the elderly who have lower alcohol tolerance and who are more impacted by alcohol due to increased comorbidities and interactions with medications, those suggested optimal cut points (in which both sensitivity and specificity are ≥ 0.80) have been determined to be ≥ 5 for the AUDIT and ≥ 4 for the AUDIT-C.[77]

For pregnant women who use alcohol, the American College of Obstetricians and Gynecologists (ACOG) "Screening and Intervention Guidelines" suggest using a validated screening tool such as the T-ACE, CRAFFT, TWEAK or AUDIT-C when screening women for risky alcohol use.[78,79]

Moreover, both Kaner, *et al.* (2007) and Gordon, *et al.* (2003) provided important evidence regarding the frequency and length of counseling. Reporting for the Cochrane Collaboration, Kaner, *et al.* (2007) determined that brief interventions in primary care – lasting generally 5 to 15 minutes for a general physician and delivered over one to four sessions – lowered alcohol consumption. Individuals screened tended not to be seeking help for alcohol problems when presenting; and the intervention they were offered included feedback on alcohol use and harms, identification of high risk situations for drinking and coping strategies, plus increased motivation and development of a personal plan to reduce drinking. Longer counseling did not significantly improve the effect; and given the weak relationship between duration of counseling and outcome, Kaner and colleagues believed that content and structure of brief interventions, rather than total time, may be more influential.[80]

Similarly, the brief advice intervention in Gordon and colleagues' (2003) study – delivered in person at each primary care site – consisted of one 10 to 15 minute session focusing on feedback from an assessment questionnaire, health and social implications of the patient's level of drinking, and advice to stop or reduce alcohol consumption. Motivational enhancement interventions – which were followed by two 10 to 15 minute booster sessions at two and six weeks – thereafter focused on feedback, consequences and goal-setting discussions, and used verbal and visual techniques to encourage patients to elaborate and discuss their thoughts regarding alcohol use and consequences. Gordon, *et al.* (2003) also significantly reported that brief advice and motivational enhancement were equally efficacious in reducing alcohol consumption in the elderly ≥ 65 years of age and their effect on drinking behavior was similar to that of nonelderly populations.[81]

In order to translate the USPSTF recommendation into Medicare policy, it is necessary to evaluate how the primary care component to the recommendation would be implemented for Medicare. The USPSTF references primary care as defined by the Institute of Medicine (1996) which was used as the basis for the recommendation and reads, "*primary care* is the provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patient, and practicing in the context of family and community." Therefore we find that the studies used to support the recommendation often excluded non primary care places of service and providers. The Medicare program recognizes numerous places of service and many would not be considered primary according to the Institute of Medicine definition. Therefore, we use this definition as the basis of excluding certain places of service from this proposed new benefit. We conclude that emergency departments, inpatient hospital settings, outpatient hospital settings, ambulatory surgical centers, independent diagnostic testing facilities, skilled nursing facilities, inpatient rehabilitation facilities and hospices are not considered primary care settings under this definition.

In order, then, to determine the eligible providers for screening and behavioral counseling we again look to the primary care definition of the Institute of Medicine. Medicare, through the Social Security Act, has already identified a list of primary care physicians and practitioners and while the purpose of such law was for incentive payments, the identified practitioners are indeed appropriate and logically fit within the scope of the USPSTF recommendation.

For the purposes of this proposed decision memorandum a primary care physician and primary care practitioner will be defined in accordance with two existing sections of the Social Security Act which have already provided such definitions (§1833(u)(6), §1833(x)(2)(A)(i)(I) and §1833(x)(2)(A)(i)(II)).

§1833(u)
(6) Physician Defined.—For purposes of this paragraph, the term “physician” means a physician described in section 1861(r)(1) and the term “primary care physician” means a physician who is identified in the available data as a general practitioner, family practice practitioner, general internist, or obstetrician or gynecologist.

§1833(x)(2)(A)(i)
(I) is a physician (as described in section 1861(r)(1)) who has a primary specialty designation of family medicine, internal medicine, geriatric medicine, or pediatric medicine; or

(II) is a nurse practitioner, clinical nurse specialist, or physician assistant (as those terms are defined in section 1861(aa)(5));

We believe our proposed coverage is consistent with the USPSTF recommendation for screening and behavioral counseling interventions in primary care to reduce alcohol misuse and are necessary to implement this proposed new benefit for Medicare beneficiaries and the Medicare program. Further, our proposed policies are consistent with the evidence reviewed.

It is important to note that there is existing Medicare coverage available for beneficiaries that are in need of alcohol assessment and brief intervention but may not fit within the indications proposed in this decision. Since the existing coverage is not considered to be a screening service, is not based on the USPSTF recommendation or the “additional preventive services” benefit under §410.64 of our regulations, then the requirements are markedly different. Please see the following publication for detailed information about this benefit:
http://www.cms.gov/MLNProducts/downloads/SBIRT_Factsheet_ICN904084.pdf

We conclude that the evidence is sufficient to determine that screening and behavioral counseling interventions in primary care to reduce alcohol misuse is appropriate for Medicare beneficiaries.

Disparities in Screening and Behavioral Counseling

Evidence exists in the literature that there are disparities in screening for alcohol misuse. For example, while Frank, *et al.* (2008) concluded that the AUDIT-C was an effective screening test in primary care patients in each of the three racial/ethnic groups (African American, Hispanic, and White), Bradley, *et al.* (2011) found that 61% of VA patients who screened positive for alcohol misuse on a mailed survey screened negative on a clinical screen despite use of the same validated AUDIT-C screening questionnaire – suggesting that many patients who could benefit from brief alcohol counseling are being missed by clinical screening. [82,83] This discordance was significantly increased among Blacks/African Americans compared with Whites, as well as among patients who had a positive survey AUDIT-C screen or received care at four of 21 VA networks. Bradley and colleagues thought the discordance may reflect social desirability bias (under-reporting of consumption due to stigma or desire to avoid discussing their drinking with providers) or bias due to differences in the way the AUDIT-C was interpreted and/or administered across racial/ethnic groups.

Additionally, Cheng, *et al.* (2011) reported that disparities were present among women who reported alcohol use during pregnancy, as well as among populations who were counseled about effects of prenatal alcohol exposure and screened for alcohol use. Self-reported alcohol use during the last three months of pregnancy, for example, was most prevalent ($P < 0.01$) among women who were 35 years of age or older, college graduates, non-Hispanic white race, married, and who used private physicians for their prenatal care. Ironically, those same groups were least likely to receive discussions about the effect of alcohol on the fetus ($P < 0.001$) or to be screened for alcohol use during pregnancy ($P < 0.01$). Cheng's study also found that women who reported alcohol consumption during pregnancy were no more likely to be screened for alcohol use or receive counseling from prenatal providers than women who did not drink, and that "targeting certain populations of women for screening may be based more on stereotype than evidence and therefore may miss those women who are the most vulnerable."[84]

Summary

Fleming, *et al.* (2002) provided the first direct RCT evidence that brief physician advice is associated with sustained reductions in alcohol use. In conjunction with the remainder of the published literature and professional guidelines, CMS thus believes there is adequate evidence that screening and behavioral counseling interventions to reduce alcohol misuse decreases alcohol consumption for identified risky or harmful drinkers, and hence reduces risk for medical problems.

There remains, however, no gold standard for screening risky/hazardous drinking behavior or one standardized approach for performing brief intervention; and having not systematically addressed the performance (sensitivity, specificity and predictive value) of alcohol screening tests, the USPSTF did not stipulate that specific screening tools (such as the AUDIT-C). Rather, the USPSTF suggested that clinicians choose screening strategies that are appropriate for their clinical population and setting, and that effective interventions to reduce alcohol misuse generally included an initial counseling session of about 15 minutes, feedback, advice and goal-setting – most of which also include further assistance and follow-up.

IX. Conclusion

The evidence is adequate to conclude that screening and behavioral counseling to reduce alcohol misuse, which is recommended with a grade of B by the U.S. Preventive Services Task Force (USPSTF) for adults, including pregnant women, in primary care settings, is reasonable and necessary for the prevention of early illness or disability, and is appropriate for individuals entitled to benefits under Part A or enrolled under Part B.

Therefore CMS proposes to cover annual alcohol screening and for those that screen positive, up to four brief, face-to-face, behavioral counseling interventions per year for Medicare beneficiaries, including pregnant women:

- Who misuse alcohol, but whose levels or patterns of alcohol consumption do not meet criteria for alcohol dependence (defined as at least three of the following: tolerance; withdrawal symptoms; impaired control; preoccupation with acquisition and/or use; persistent desire or unsuccessful efforts to quit; sustains social, occupational, or recreational disability; use continues despite adverse consequences); and

- Who are competent and alert at the time that counseling is provided; and

- Whose counseling is furnished by qualified primary care physicians or other primary care practitioners in a primary care setting.

Each of the behavioral counseling interventions should be consistent with the 5A's approach that has been adopted by the USPSTF to describe such services:

1. **Assess**: Ask about/assess behavioral health risk(s) and factors affecting choice of behavior change goals/methods.
2. **Advise**: Give clear, specific, and personalized behavior change advice, including information about personal health harms and benefits.
3. **Agree**: Collaboratively select appropriate treatment goals and methods based on the patient's interest in and willingness to change the behavior.
4. **Assist**: Using behavior change techniques (self-help and/or counseling), aid the patient in achieving agreed-upon goals by acquiring the skills, confidence, and social/environmental supports for behavior change, supplemented with adjunctive medical treatments when appropriate.
5. **Arrange**: Schedule follow-up contacts (in person or by telephone) to provide ongoing assistance/support and to adjust the treatment plan as needed, including referral to more intensive or specialized treatment.

For the purposes of this decision memorandum, a primary care setting is defined as one in which there is provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community. Emergency departments, inpatient hospital settings, outpatient hospital settings, ambulatory surgical centers, independent diagnostic testing facilities, skilled nursing facilities, inpatient rehabilitation facilities and hospices are not considered primary care settings under this definition.

For the purposes of this proposed decision memorandum a “primary care physician” and “primary care practitioner” will be defined based on two existing sections of the Social Security Act(§1833(u)(6), §1833(x)(2)(A)(i)(I) and §1833(x)(2)(A)(i)(II)).

§1833(u)
(6) Physician Defined.—For purposes of this paragraph, the term “physician” means a physician described in section 1861(r)(1) and the term “primary care physician” means a physician who is identified in the available data as a general practitioner, family practice practitioner, general internist, or obstetrician or gynecologist.

§1833(x)(2)(A)(i)
(I) is a physician (as described in section 1861(r)(1)) who has a primary specialty designation of family medicine, internal medicine, geriatric medicine, or pediatric medicine; or

(II) is a nurse practitioner, clinical nurse specialist, or physician assistant (as those terms are defined in section 1861(aa)(5));

We are requesting public comments on this proposed determination pursuant to section 1862(l) of the Social Security Act. After considering the public comments, we will make a final determination and issue a final decision memorandum.

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1 http://www.uspreventiveservicestaskforce.org/uspstf/uspsdrin.htm (April 2004)

2 http://pubs.niaaa.nih.gov/publications/10report/chap01a.pdf

3 Kaner, *et al.* (2007)

4 Dependence has been defined as “at least three of the following: tolerance; withdrawal symptoms; impaired control; preoccupation with acquisition and/or use; persistent desire or unsuccessful efforts to quit; sustains social, occupational, or recreational disability; use continues despite adverse consequences.” (Reid, *et al.* 1999, Table 1, as cited by Whitlock *et al.’s* 2004 Evidence Summary for the USPSTF)

5 Saitz (2005)

6 http://pubs.niaaa.nih.gov/publications/Practitioner/CliniciansGuide2005/guide.pdf (NIAAA Clinician’s Guide, 2005)

7 Saitz 2005

8 No funding agencies (RWJ, SAMHSA or CSAT) played an active role in preparation, review or editing.

9 Ronksley, *et al.* (2011)

10 Brien, *et al.* (2011)

11 42 CFR 410.64. See also 75 Fed. Reg. 73, 170, 73, 615 (November 27, 2010).

12 Cochrane and Holland (1971)

13 http://pubs.niaaa.nih.gov/publications/Assesing%20Alcohol/selfreport.htm

14 http://pubs.niaaa.nih.gov/publications/arh25-3/204-209.htm

15 Fiellin, *et al.* (2000)

16 Bradley, *et al.* (2007)

17 http://pubs.niaaa.nih.gov/publications/Assesing%20Alcohol/InstrumentPDFs/14_AUDIT.pdf

18 http://www.niaaa.nih.gov/Publications/EducationTrainingMaterials/Documents/Audit.pdf

19 http://pubs.niaaa.nih.gov/publications/Assesing%20Alcohol/InstrumentPDFs/16_CAGE.pdf

20 http://pubs.niaaa.nih.gov/publications/Assesing%20Alcohol/InstrumentPDFs/42_MAST.pdf

21 Bush, *et al.* (1998)

22 Bradley, *et al.* (2007)

23 Burns, *et al.* (2010)

24 http://pubs.niaaa.nih.gov/publications/arh25-3/204-209.htm

25 http://pubs.niaaa.nih.gov/publications/arh28-2/78-79.htm (CAGE, T-ACE and AUDIT questionnaires)

26 http://pubs.niaaa.nih.gov/publications/arh25-3/204-209.htm

27 http://pubs.niaaa.nih.gov/publications/Assesing%20Alcohol/InstrumentPDFs/74_TWEAK.pdf

28 http://www.uspreventiveservicestaskforce.org/uspstf/uspsdrin.htm (April 2004)

29 http://www.uspreventiveservicestaskforce.org/3rduspstf/alcohol/alcomisrs.htm (USPSTF Recommendation Statement, April 2004)

30 Whitlock, *et al.* (2004)

31 Whitlock, *et al.* (2002)

32 Drinks and units were converted to grams of alcohol using either a conversion factor or, if none was reported, using a factor appropriate for the country where the study was conducted. Eight grams of alcohol equals one unit, but definitions of heavy drinking and binge drinkers varied between trials.

33 Kaner, *et al.* (2007 Cochrane Review)

34 Bertholet, *et al.* (2005)

35 Ballesteros, *et al.* (2004)

36 McGinnis and Foege (1993)

37 Mokdad, *et al.* (2004)

38 Bailey and Sokol (2008)

39 Nilsen (2009)

40 Cheng, *et al.* (2011)

41 Although this evaluation regarding the cost-effectiveness of screening for alcohol misuse used quality-adjusted life years (QALYs), CMS does not have and is not establishing in this proposed decision memorandum a coverage threshold for QALYs. See 1182(e) of the Social Security Act.

42 Solberg, *et al.* (2008)

43 Fleming, *et al.* (2002)

44 Gordon, *et al.* (2003)

45 The proportion of people with alcohol misuse who have a positive test result, also called the true positive rate.

46 The proportion of people without alcohol misuse who have a negative test result, also called the true negative rate.

47 Frank, *et al.* (2008)

48 Aalto, *et al.* (2010)

49 http://pubs.niaaa.nih.gov/publications/Practitioner/CliniciansGuide2005/guide.pdf (NIAAA Clinician's Guide, 2005)

50 http://www.ncbi.nlm.nih.gov/books/NBK14467/

51 http://www.ncbi.nlm.nih.gov/books/NBK26330/

52 http://www.ncbi.nlm.nih.gov/books/NBK26263/#A48483

53 http://www.aafp.org/online/en/home/clinical/publichealth/alcohol.html

54 http://www.aafp.org/online/en/home/clinical/exam/alcoholmisuse.html

55 http://www.acog.org/departments/healthIssues/FASDToolKit.pdf (Screening and Intervention Guidelines, pages 6 and 7)

56 http://www.acog.org/departments/healthIssues/AdditionalScreeningTools.pdf (Additional Screening and Intervention Tools)

57 http://www.apha.org/NR/rdonlyres/B03B4514-CCBA-47B9-82B0-5FEB4D2DC983/0/SBImanualfinal4_16.pdf

58 42 CFR 410.64

59 http://www.uspreventiveservicestaskforce.org/uspstf/uspsdrin.htm (April 2004)

60 McGinnis and Foege (1993)

61 http://www.uspreventiveservicestaskforce.org/3rduspstf/alcohol/alcomisrs.htm (USPSTF Recommendation Statement, April 2004)

62 Whitlock, *et al.* (2004)

63 Mokdad, *et al.* (2004)

64 Fleming, *et al.* (2002)

65 http://www.uspreventiveservicestaskforce.org/3rduspstf/alcohol/alcomisrs.htm (USPSTF Recommendation Statement, April 2004)

66 Bailey and Sokol (2008)

67 Cheng, *et al.* (2011)

68 Nilsen (2009)

69 http://www.uspreventiveservicestaskforce.org/3rduspstf/alcohol/alcomisrs.htm (USPSTF Recommendation Statement, April 2004)

70 St. John, *et al.* (2009)

71 Malet, *et al.* (2009)

72 Moore, *et al.*(2002)

73 Gordon, *et al.* (2003)

74 Beullens, *et al.* (2004)

75 Malet, *et al.* (2009)

76 Aalto, *et al.* (2010)

77 Aalto, *et al.* (2010)

78 http://www.acog.org/departments/healthIssues/FASDToolKit.pdf (Screening and Intervention Guidelines, pages 6-7)

79 http://www.acog.org/departments/healthIssues/AdditionalScreeningTools.pdf (Additional Screening and Intervention Tools)

80 Kaner, *et al.* (2007 Cochrane Review)

81 Gordon, *et al.* (2003)

82 Frank, *et al.* (2008)

83 Bradley, *et al.* (2011)

84 Cheng, *et al.* (2011)

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Bibliography

42 CFR 410.64 (Title 42, Code of Federal Regulations, Additional Preventive Services)

http://www.aafp.org/online/en/home/clinical/exam/alcoholmisuse.html (AAFP Recommendations, 2004)

http://www.aafp.org/online/en/home/clinical/publichealth/alcohol.html (AAFP Brief Alcohol Screening and Intervention in Family Medicine)

http://archinte.ama-assn.org/cgi/reprint/158/16/1789.pdf (AUDIT-C screening questionnaire)

http://pubs.niaaa.nih.gov/publications/arh25-3/204-209.htm (Alcohol-Screening Instruments for Pregnant Women, NIAAA 2001)

http://pubs.niaaa.nih.gov/publications/arh28-2/78-79.htm (The CAGE, T-ACE and AUDIT questionnaires)

http://pubs.niaaa.nih.gov/publications/Assesing%20Alcohol/factsheets.htm (NIAAA Instrument Fact Sheets)

http://pubs.niaaa.nih.gov/publications/Assesing%20Alcohol/InstrumentPDFs/14_AUDIT.pdf (AUDIT screening questionnaire)

http://pubs.niaaa.nih.gov/publications/Assesing%20Alcohol/InstrumentPDFs/16_CAGE.pdf (CAGE screening questionnaire)

http://pubs.niaaa.nih.gov/publications/Assesing%20Alcohol/InstrumentPDFs/42_MAST.pdf (MAST screening questionnaire)

http://pubs.niaaa.nih.gov/publications/Assesing%20Alcohol/InstrumentPDFs/74_TWEAK.pdf (TWEAK screening questionnaire)

http://pubs.niaaa.nih.gov/publications/Assesing%20Alcohol/selfreport.htm (NIAAA Self–Report Screening for Alcohol Problems Among Adults, 2004)

http://pubs.niaaa.nih.gov/publications/Practitioner/CliniciansGuide2005/guide.pdf (NIAAA Clinician's Guide, 2005)

http://www.acog.org/departments/healthIssues/AdditionalScreeningTools.pdf (Additional Screening and Intervention Tools)

http://www.acog.org/departments/healthIssues/FASDToolKit.pdf (Screening and Intervention Guidelines, pages 6-7)

http://www.cdc.gov/ncbddd/fasd/acog_toolkit.html (Fetal Alcohol Spectrum Disorders Prevention Tool Kit for Women's Health Care Providers)

http://www.cms.gov/medicare-coverage-database/details/nca-view-public-comments.aspx?NCAId=249&ExpandComments=n&ver=1&NcaName=Screening+and+Behavioral+Counseling+Interventions+in+Primary+Care+to+Reduce+Alcohol+Misuse&bc=BEAAAAAAEAAA& (Public Comments for this Proposed Decision Memorandum)

http://www.niaaa.nih.gov/Publications/EducationTrainingMaterials/Documents/Audit.pdf (The AUDIT Questionnaire, excerpted from NIH Publication No. 07-3769)

http://www.ncbi.nlm.nih.gov/books/NBK14467/ (TIP 26: Substance Abuse Among Older Adults, SAMHSA 2008)

http://www.ncbi.nlm.nih.gov/books/NBK26263/#A48483 (TIP 26, Executive Summary and Recommendations, SAMHSA 2008)

http://www.ncbi.nlm.nih.gov/books/NBK26330/ (TIP 26, Chapter 2: Alcohol, SAMHSA 2008)

http://www.uspreventiveservicestaskforce.org/uspstf/grades.htm#pre (USPSTF Grade Definitions Prior to May 2007)

http://www.uspreventiveservicestaskforce.org/uspstf/uspsdrin.htm (USPSTF Summary of Recommendations/Supporting Documents, April 2004)

http://www.uspreventiveservicestaskforce.org/3rduspstf/alcohol/alcomisrs.htm (USPSTF Recommendation Statement, April 2004)

Aalto M, Alho H, Halme J, *et al.* The alcohol use disorders identification test (AUDIT) and its derivatives in screening for heavy drinking among the elderly. *International Journal of Geriatric Psychiatry* 2010. DOI: 10.1002/gps.2498 PMID: 20661878

American Public Health Association and Education Development Center, Inc. (2008). Alcohol screening and brief intervention: A guide for public health practitioners. Washington DC: National Highway Traffic Safety Administration, U.S. Department of Transportation. Available at: http://www.apha.org/NR/rdonlyres/B03B4514-CCBA-47B9-82B0-5FEB4D2DC983/0/SBImanualfinal4_16.pdf Accessed May 4, 2011.

Bailey B and Sokol R. Pregnancy and alcohol use: evidence and recommendations for prenatal care. *Clinical Obstetrics and Gynecology* 2008 June;51(2):436-444. PMID: 18463472

Ballesteros J, Gonzalez-Pinto A, Querejeta I, *et al.* Brief interventions for hazardous drinkers delivered in primary care are equally effective in men and women. *Addiction* 2004 January;99(1):103-108. PMID: 14678068

Bertholet N, Daeppen J, Wietlisbach V, *et al.* Reduction of alcohol consumption by brief alcohol intervention in primary care: systematic review and meta-analysis. *Archives of Internal Medicine* 2005 May 9;165(9):986-995. PMID: 15883236

Beullens J and Aertgeerts B. Screening for alcohol abuse and dependence in older people using DSM criteria: a review. *Aging & Mental Health* 2004 January; 8(1): 76–82. PMID: 14690871

Bradley K, DeBenedetti A, Volk R, *et al*. AUDIT-C as a brief screen for alcohol misuse in primary care. *Alcoholism: Clinical and Experimental Research* 2007 July;31(7)1208-1217. PMID: 17451397

Bradley K, Lapham G, Hawkins E, *et al.* Quality concerns with routine alcohol screening in VA clinical settings. *Journal of General Internal Medicine* 2011 March;26(3):299-306. PMID: 20859699

Brien S, Ronksley P, Turner B, *et al.* Effect of alcohol consumption on biological markers associated with risk of coronary heart disease: systematic review and meta-analysis of interventional studies. *British Medical Journal* 2011 Feb 22;342:d636. DOI: 10.1136/bmj.d636. PMID: 21343206

Burns E, Gray R and Smith L. Brief screening questionnaires to identify problem drinking during pregnancy: a systematic review. *Addiction* 2010 April;105(4):601-614. PMID: 20403013

Bush K, Kivlahan D, McDonell M, *et al.* The AUDIT-C alcohol consumption questions (AUDIT-C) *Archives of Internal Medicine* 1998;158:1789-1795. PMID: 9738608

Cheng D, Kettinger L, Uduhiri K, *et al.* Alcohol consumption during pregnancy: prevalence and provider assessment. *Obstetrics & Gynecology* 2011 February;117(2 Pt 1):212-217. PMID: 21252732

Cochrane A and Holland W. Validation of screening procedures. *British Medical Bulletin* 1971;27(1):3-8. PMID: 5100948

Fiellin D, Reid C, and O'Connor P. Screening for alcohol problems in primary care. *Archives of Internal Medicine* 2000;160:1977-1989. PMID: 10888972

Fleming M, Mundt M, French M, *et al.* Brief physician advice for problem drinkers: long-term efficacy and benefit-cost analysis. *Alcoholism: Clinical and Experimental Research* 2002;26(1):36-43. PMID: 11821652

Frank D, DeBenedetti A, Volk R, *et al.* Effectiveness of the AUDIT-C as a screening test for alcohol misuse in three race/ethnic groups. *Journal of General Internal Medicine* 2008 June;23(6):781-787. PMID: 18421511

Gordon A, Conigliaro J, Maisto, *et al.* Comparison of consumption effects of brief interventions for hazardous drinking elderly. *Substance Use & Misuse* 2003; June;38(8):1017-1035. PMID: 12901447

Kaner E, Dickinson H, Beyer F, *et al.* Effectiveness of brief alcohol interventions in primary care populations. *Cochrane Database of Systematic Reviews* 2007;(2):CD004148. DOI: 10.1002/14651858.CD004148.pub3. PMID: 17443541 Edited (no change to conclusions), published in Issue 4, 2009. Available online: http://onlinelibrary.wiley.com/o/cochrane/clsysrev/articles/CD004148/frame.html Accessed May 4, 2011.

Maciosek M, Coffield A, Edwards N, *et al.* Priorities among effective clinical preventive services: results of a systematic review and analysis. *American Journal of Preventive Medicine* 2006 July;31(1):52-61. PMID: 16777543

Malet L, Brousse G and Llorca P. CAGE unsound for alcohol misuse in seniors. *International Journal of Geriatric Psychiatry* 2009;24:434-435 PMID: 19301300

Measuring the Health Risks and Benefits of Alcohol. In: *The Tenth Special Report to the U.S. Congress on Alcohol and Health*. Rockville, MD: National Institute on Alcohol Abuse and Alcoholism; 2000. NIH Publication No. 00-1583 Available online: http://pubs.niaaa.nih.gov/publications/10report/chap01a.pdf Accessed May 4, 2011.

Mokdad A, Marks J, Stroup D, *et al.* Actual causes of death in the United States, 2000. *Journal of the American Medical Association* 2004 March 10;291(10):1238-1245. PMID: 15010446

Moore A, Seeman T, Morgenstern H, *et al.* Are there differences between older persons who screen positive on the CAGE questionnaire and the Short Michigan Alcoholism Screening Test-Geriatric Version? *Journal of the American Geriatric Society* 2002 May;50(5):858-862. PMID: 12028172

Nilsen P. Brief alcohol intervention to prevent drinking during pregnancy: an overview of research findings. *Current Opinion in Obstetrics and Gynecology* 2009;21:496–500. PMID: 19797951

Reid M, Fiellin D, and O'Connor. Hazardous and harmful alcohol consumption in primary care. *Archives of Internal Medicine* 1999;159:1681-1689. PMID: 10448769

Ronksley P, Brien S, Turner B, *et al.* Association of alcohol consumption with selected cardiovascular disease outcomes: a systematic review and meta-analysis. *British Medical Journal* 2011 Feb 22;342:d671. DOI: 10.1136/bmj.d671. PMID: 21343207

Saitz R. Clinical practice. Unhealthy alcohol use. *New England Journal of Medicine* 2005;352:596-607. PMID: 15703424

Solberg L, Maciosek M and Edwards N. Primary care intervention to reduce alcohol misuse ranking its health impact and cost effectiveness. *American Journal of Preventive Medicine* 2008 February;34(2):143-152. PMID: 18201645

St. John P, Montgomery P, and Tyas S. Alcohol screening and case finding instruments. *International Journal of Geriatric Psychiatry* 2009;24:433-434. DOI: 10.1002/gps.2237

Whitlock E, Orleans C, Pender N, *et al.* Evaluating primary care behavioral counseling interventions. An evidence-based approach. *American Journal of Preventive Medicine* 2002;22(4):267-284. PMID: 11988383

Whitlock E, Polen M, Green C, *et al.* Behavioral counseling interventions in primary care to reduce risky/harmful alcohol use by adults: a summary of the evidence for the U.S. Preventive Services Task Force. *Annals of Internal Medicine* 2004; 140(7):557-568. PMID: 15068985

Whitlock E, Green C, and Polen M. *Behavioral Counseling Interventions in Primary Care to Reduce Risky/Harmful Alcohol Use. Systematic Evidence Review*. No. 30. (Prepared by the Oregon Evidence-based Practice Center under Contract No. 290-97-0018). Rockville, MD: Agency for Healthcare Research and Quality. April 2004. PMID: 20722127

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